UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

SUBHASH PATEL, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. KONINKLIJKE PHILIPS N.V., FRANS VAN HOUTEN, and ABHIJIT BHATTACHARYA, Defendants.	Case No. 1:21-cv-04606-MKB-MMH

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules and Regulations

Other Authorities

PRELIMINARY STATEMENT

This is a federal securities class action on behalf of a class of shareholders in Koninklijke Philips N.V. ("Philips" or the "Company"), seeking to recover damages caused by misrepresentations, largely made in Philips' SEC filings and during earnings calls with investors, about the financial success, safety, and regulatory compliance of certain Philips devices used to treat sleep and various breathing conditions. The Complaint[1] asserts claims for violations of the federal securities laws under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.

Throughout the Class Period, Philips's subsidiary, Philips Respironics, Inc. manufactured several popular Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices ("Devices"). Many of these devices utilized polyester-based polyurethane (PE-PUR) foam for sound abatement purposes. ¶2. Throughout the Class Period, Philips sold millions of these devices. ¶3. Unbeknownst to the market, the foam in these devices was subject to degradation, which meant that foam particles could enter the Devices' air pathway and be ingested or inhaled by the user. ¶4. The degrading foam could also "off-gas certain chemicals" that possessed toxic properties with carcinogenic effects. *Id*. By the end of 2015 at the latest, Philips had received multiple user complaints about the foam degradation. ¶5.

Over the years, complaints kept pouring in. Philips (either itself or through its subsidiary Philips Respironics) generated internal reports related to those complaints, which repeatedly documented the foam degradation and even found that it presented "a significant biological risk" to patients through, among other things, the emission of Volatile Organic Compounds with carcinogenic effects. ¶¶6, 116, 119, 122, 329. Philips did not share these reports with the public, however. ¶6. The Company also did not adequately address any of the issues raised in these

[1] "¶__" refers to the Amended Class Action Complaint (the "Complaint"). Dkt. No. 16.

reports. *Id*. For the most part—with the possible exception of a part replacement to one type of marketed device (a procedure not reported to the FDA, as it was required to be under FDA regulations)—Philips kept all devices utilizing the Foam on the market without any changes. *Id*. Before mid-2021, Philips never disclosed any issues with the Devices. ¶7. Instead, it repeatedly promoted the Devices as safe and well-received products that contributed to Philips' bottom-line, and claimed that it was complying with the applicable FDA regulations. *Id*. Philips not only continued to tout the foam products that were already on the market, but also introduced new products containing the foam, such as the E30 ventilator. ¶8.

On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips disclosed for the first time that device user reports had led to a discovery that "the [PE-PUR] foam may degrade under certain circumstances ... " ¶9. A reserve of EUR 250 million was taken solely to repair the units in the field. *Id*. The Company claimed that "[t]he majority of the affected devices are in the first-generation DreamStation product family" and mentioned no other product, despite knowing that other products contained the same type of foam. ¶10. Eventually, Philips had no option but to recall the rest of the Devices, which included the E30 ventilators. ¶12. The FDA classified the recall as Class I, for the rare situations involving "*a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."* ¶15. To date, Philips took a EUR 500 million reserve to account for the recall. ¶17.

On November 12, 2021, the FDA took the unusual step of reporting lengthy findings of its site investigation of Philips Respironics ("Form 483").[2] ¶20. Among other things, the FDA found that: Philips Respironics has "not sufficiently demonstrated that other devices, also containing polyester polyurethane foam, should not be included in [the] ongoing recalls" (¶349; Form 483 at

[2] Form 483 is an exhibit to Defendants' brief.

1); there were at least fourteen instances, assessments, and/or test reports, starting as early as April 2016, "where your firm was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions" (¶351; Form 483 at 3); "[a] correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA" (¶371); "[p]rocedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established" (¶375); and "your firm became aware of this issue and related field complaints in at least 2015 or earlier." Moreover, the FDA found that "management with executive responsibility" attended meetings at least "since [] 2019" where the foam degradation issues were discussed. ¶373; Form 483 at 24. The management with executive responsibility included Philips' Sleep and Respiratory Care Business Leader and the Head of Quality. ¶374.

When news about the Devices and Philips' knowledge emerged through a series of corrective disclosures, Philips' stock price plunged, causing investors hundreds of millions of dollars in damages.

I. STATEMENT OF FACTS

A. The Nature of Philips' Business and the Related Regulatory Framework

During the Class Period, Philips had three main reportable segments: Diagnosis & Treatment; Connected Care; and Personal Health (2020 20-F at §6.3), and reported sales from the Company's Sleep and Respiratory Care business within the Personal Health segment until January 1, 2019, and thereafter under the Connected Care segment. ¶206. Approximately 60% of Sleep and Respiratory Care revenue derived from the sale of the recalled Devices. ¶¶17, 340.

Philips repeatedly represented to investors that its business success depended on the quality of its products and its compliance with global regulations and standards. *See e.g.* ¶293. The Company claimed that it was taking the necessary precautions to ensure quality through the

standardization and adoption of industry best practices via its Quality Management System. ¶¶68, 180, 245, 293. Specifically, Philips told investors that it was actively maintaining Quality Management Systems that establish processes for its product design, manufacturing and distribution processes, and that these standards complied with Food and Drug Administration (FDA)/International Organization for Standardization (ISO) requirements. ¶80. Specifically, "[m]anagement with executive responsibility" was required to "establish [the Company's] policy for, and commitment to, quality," and "[m]anagement with executive responsibility" was required to "ensure that the quality policy is understood, implemented and maintained at all levels of the organization." ¶66. "Management with executive responsibility" was also required to "review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the [FDA regulations] and [the Company's] established quality policy and objectives." *Id*. The Company was required to conduct quality audits for the management with executive responsibility's review. *Id*. The Company was also required to "establish and maintain procedures to control product that does not conform to specified requirements," addressing among other things "the identification, documentation, [and] evaluation" of the nonconforming products. ¶67.

Each of the Devices was subject to the FDA's Quality System Regulation pursuant to Section 820 of Title 21 of the Code of Federal Regulation. ¶65. Each of the Devices was subject to performance standards set by the FDA/ISO to provide reasonable assurance of the safety and effectiveness of the Devices, including pursuant to Section 514 of the Federal Food, Drug, and Cosmetic Act ("FD&CA"). ¶55. For each Device, Philips was required to submit an annual report to the FDA certifying that the Company was engaged in, among other things, the continuing evaluation of the safety effectiveness and reliability of the Devices for their intended use. ¶57.

Philips was also required to establish Corrective and Preventive Action ("CAPA") programs, including identifying and investigating product and quality problems with the Devices. ¶62.

B. For Years, Philips Knew of Problems With Foam Degradation But Concealed Them From Investors

An investigation conducted by the FDA at Philips Respironics, the subsidiary that manufactured the Devices, revealed numerous instances of customer complaints and internal tests conducted by or at the request of Philips or its subsidiary that showed that the foam in the Devices was susceptible to degradation. Philips did not disclose this heightened risk to investors.

For example, as early as October 20, 2015, Philips Respironics sent an email to its foam supplier implying that a customer made the company aware of polyester polyurethane foam degradation issues. ¶81. On November 25, 2015, Philips Respironics learned that another Philips entity already conducted a preventative maintenance servicing procedure on some of the Devices in response to issues and complaints of foam degradation. Form 483 at 21. At least two of these complaints were from Trilogy 100 users and at least some others were from Trilogy 200 users. ¶81. An internal report dated April 1, 2016, which utilized field samples obtained in October 2015 from the Trilogy 100 ventilator, "document[ed] base polymer cleavage and embrittlement of the returned foam material of the related field samples," meaning the foam was disintegrating and breaking. ¶87. Then, on August 5, 2016, Philips' foam supplier sent an email advising Philips Respironics that degradation of the foam was "likely" and could occur somewhat quickly. ¶88.

Another internal report dated August 30, 2016, responding to customer complaints of foam degradation studied the foam in the Company's Trilogy 200 ventilator and found "color changes" and "bad resistance against high humidity in combination with high temperature." Form 483 at 4. A follow-up internal study dated November 25, 2016, indicated that different types of foams showed significant resistance to degradation but that the polyester urethane foams did not perform

well. ¶91. A subsequent test report dated December 12, 2018, found that "[t]here was a problem of degradation of the damping foam in Trilogy Respironics appliance in 2016." Form 483 at 5. A test report dated May 22, 2019, concluded that additional polyurethane samples were analyzed for foam degradation and showed a "chemical reaction" occurring when the foam was exposed to high heat and humidity. *Id*. The report refers to "significant evidence" but the details are redacted. *Id*.

A January 30, 2020, internal analysis documented that the DreamStation (1) CPAP device failed emissions testing for Volatile Organic Compounds ("VOCs") and Aldehydes. *Id*. at 6. The related tests were conducted between January 18, 2019, and January 25, 2019, and between January 25, 2019, and February 1, 2019. *Id*. Another biological risk assessment test dated July 2, 2020, found that "[c]ompounds of concern were identified as analytes ... with potential for carcinogenicity, mutagenicity, and systemic toxicity." *Id*. at 7. The report stated that "the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern and the severity of harm is crucial with respect to both the 30 kg and 70 kg patient populations of the System One medical device." *Id*. Yet another biological risk test assessment of the degraded polyester-polyurethane foam, dated December 10, 2020, found that "potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from" the degraded foam. *Id*. at 7-8. The results showed mutagenic responses in both bacterial and mammalian systems. *Id*. at 8.

Still, Philips continued to tout the qualities of its polyurethane products without a hint of their degradation, concealing the real risk associated with them. ¶¶8, 27, 76, 86.

More undisclosed reports of toxicology followed. On January 11, 2021, an internal biocompatibility risk assessment for degraded foam in CPAP and ventilator units concluded that "[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure." Form 483 at 8. Another internal analysis dated January 13,

2021, reporting on tests of the foam used in "various Sleep and Respiratory Care Products" stated that "the test article is considered to be mutagenic," and that the product "is considered to have a cytotoxic potential." *Id*. at 9-10. And an internal biological risk assessment report dated January 22, 2021, found that the degraded polyester polyurethane foam "is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to" the foam as it includes "mutagenic responses in both a bacterial and mammalian system." *Id*. at 10.

An FDA search of Philips' database disclosed "over 222,000 complaints" that included the keywords "contaminants, particles, foam, debris, airway, particulate, airpath, and black." ¶357. Of those, at least 110 complaints from 2014 to 2017 were directly related to foam degradation. *Id*. According to the FDA, by 2018, only around 20,000 of the over 175,000 complaints that came up in a keyword search involved Trilogy Devices, meaning approximately 155,000 involved ***other*** Philips Devices (in addition to the Trilogy devices) and hit on the terms contaminants, particles, foam, debris, airway, particulate, airpath, and black. ¶96. In other words, Philips knew that the foam degradation issue was not limited to the Trilogy Devices.

C. The Truth About the Risks Related to the Devices Slowly Emerges

On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips partly disclosed for the first time that Device user reports had led to a discovery that "the [PE-PUR] foam may degrade under certain circumstances ...." ¶304. But even this tardy disclosure was incomplete as Philips failed to alert the market of the full scale of the problem. ¶305. Instead, Philips sought to minimize the issue by claiming that "[t]he majority of the affected devices are in the first-generation DreamStation product family," and failed to mention that numerous other products were also affected because they contained the same type of foam. *Id*. Philips announced that it was taking a provision of 250 million euros, which was solely for repair of units in the field. *Id*.

During the 1Q-2016 earnings call, Defendant Van Houten told investors that "[t]he issue

with the DreamStation 1 family and related products ***come out of our post-market surveillance where we have picked up reports from users that lead us to do this warning***." ¶306; *see also* ¶308. Van Houten misleadingly claimed that the discovery of the foam degradation "is early stage because we wanted to go out immediately and we are also in parallel then engaging the regulatory agencies with whom we have to detail out the field safety notice as is customary practice." ¶308. As explained above, however, these post-market user reports existed ***as early as 2015***, and ***Philips' own tests and analysis showed foam degradation as early as April 2016***. *Supra* at 1-3, 5.

As time went on, it became clear that Philips' April "company update" was not enough—the devices needed to be recalled. On June 14, 2021, Philips issued a supposedly voluntary recall of certain of its Bi-Level PAP and CPAP devices, as well as mechanical ventilators. ¶316. Philips disclosed that it "determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals ...." ¶319. Philips acknowledged that "[t]hese issues can result in serious injury which can be life-threatening…" ¶322.

On July 22, 2021, the FDA identified the recall as Class I, ***the most serious type of recall***, where there is a "reasonable probability that the use of or exposure to a violative product ***will cause serious adverse health consequences or death***." ¶329.

In a press release reporting its Q2 2021 results, Philips highlighted the huge impact the recall had on the Company's balance sheet, with sales in the Connected Care segment plunging 16% from the prior period. ¶332. Philips also announced that it was taking an additional EUR 250 million reserve—for a total of EUR 500 million reserve in the first half of 2021—to account for the impacted Devices. ¶333.

The news about the true state of the Devices and the associated recall and FDA investigation resulted in multiple plunges in the price of Philips' securities, causing financial harm to investors. *See, e.g.*, ¶¶ 314, 328, 341, 382. Analysts commented that the issues raised by the FDA investigation are "likely to raise perceived risk" of investing in the Company, and noted that "Philips may have known about the deficiencies for several years." *See* ¶¶384-85.

D. Post-Class Period Developments

There have been several updates since the recall and subsequent FDA revelations. Users bringing lawsuits against Philips have alleged that they have developed multiple types of cancers as a result of their use of the Devices. ¶389. On December 23, 2021, Philips issued a press release, downplaying the long-term health impact of the devices. ¶390. On March 10, 2022, the FDA issued a notification order requiring the maker of the devices to make sufficient disclosures about the foam degradation, explaining that it "***has determined that this order is necessary to eliminate the unreasonable risk of harm*** posed by the recalled products, ***because the company's notification efforts to date have been inadequate***."[3]

II. ARGUMENT

In evaluating a Rule 12(b)(6) motion to dismiss, the Court must accept the truth of the facts alleged and draw all reasonable inferences in Plaintiffs' favor. *Glob. Network Commc'ns, Inc. v. City of New York*, 458 F.3d 150, 154 (2d Cir. 2006). Plaintiffs need only allege "enough facts to state a claim for relief that is plausible on its face[.]" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Rule 10b-5(b) makes it unlawful for a person "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. §240.10b-5(b). "[T]he

[3] *See* https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health.

materiality of an omission is a mixed question of law and fact, [thus] courts often will not dismiss a securities fraud complaint at the pleading stage of the proceedings, unless reasonable minds could not differ on the importance of the omission." *Halperin v. eBanker USA.COM, Inc.*, 295 F.3d 352, 356–57 (2d Cir. 2002).

A. The Complaint Pleads Actionable Statements About the Success of the Devices

"Upon choosing to speak, one must speak truthfully about material issues." *Caiola v. Citibank, N.A.*, 295 F.3d 312, 331 (2d Cir. 2002). Throughout the Class Period, Defendants repeatedly portrayed the Devices as innovative products that *improved* patient outcomes, have been well-received, and were safe. *See, e.g.*, ¶¶126, 140, 221. For example, Defendants claimed that the "DreamStation Go delivers ... clinically-proven performance and comfort, for reliable, convenient therapy on-the-go," a product that "enhance[s] patient care and quality of life." ¶157; *see similarly* ¶171 (characterizing Trilogy ventilator as "clinically-validated" and "expected to ... reduce hospital admissions while improving the patient experience."); *see also* ¶176. In April 2017 Defendants touted positive results from a study sponsored by Philips supposedly showing "significant decreases in ... hospitalization rates for severe chronic obstructive pulmonary disease ... with the use of ... Philips Trilogy 100," emphasizing that the product "is the most widely dispensed portable ventilator in North America." ¶¶159-60.

Similarly, Defendants claimed that the Respironics E30 ventilator "can be safely used" and was "designed ... by a team deeply experienced in respiratory care[.]" ¶248. During Philips' earnings call held on April 20, 2020, Defendant Van Houten characterized the E30 ventilator as "an adaptation from a bi-plan ventilator, to which we have changed the software, added sensors, added filters, so that it is safe and suitable for critical care." ¶255. Defendant Philips also lauded the BiPAP A40 ventilator as a "non-invasive" product that treats patients with "targeted therapy

to reduce symptoms and increase their comfort while sleeping," and also claimed that the E30 "was developed ... while also complying to medical device quality standards." ¶¶78, 282.

These and other similar statements were false and misleading at the time they were made because they failed to disclose that the foam used in the Devices was experiencing consistent degradation, and posed a significant risk to patients' health. Once Defendants chose to tout the Devices, they were duty-bound to tell investors the whole truth. *See Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250 (2d Cir. 2014). In *Omnicare v. Laborers Dist. Council Const. Indus. Pension Fund,* 575 U.S. 175, 183-84 (2015), for example, the Supreme Court explained that a CEO's assertion that the "'The TVs we manufacture have the highest resolution available on the market' ... is not mere puffery, but a determinate, verifiable statement about her company's TVs" that can be actionable if false or misleading. Likewise, in *Oklahoma Police Pension & Ret. Sys. v. LifeLock, Inc.*, 780 F. App'x 480, 483 (9th Cir. 2019), the Ninth Circuit held that plaintiffs "adequately alleged falsity" because defendants misled investors when they chose to "tout their products' capabilities" but did not disclose "adverse information that cuts against the positive information."[4] Moreover, Defendants repeatedly praised the qualities of the Devices, "creat[ing] the reasonable understanding among investors" that the company "attached considerable significance" to the topic, and rendering them uniquely important to investors. *Weiner v. Quaker*

[4] Similarly, in *City of Monroe Emps.' Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 672-74 (6th Cir. 2005), the Sixth Circuit found that statements touting tires' safety, such as "[p]roperly inflated and maintained Firestone ATX ... tires are among the safest tires on the road today" and "the objective data clearly reinforces our belief that these are high-quality, safe tires" were actionable, and "could be deemed a material misrepresentation by a reasonable fact-finder." And in *Hanon v. Dataproducts Corp.*, 976 F.2d 497, 501-03 (9th Cir. 1992), the Ninth Circuit found that statements praising the technological advancements of a company's printer were misleading where the printer had technical problem. *See similarly In re Allergan PLC Sec. Litig.*, 2019 WL 4686445, at **1, 22-25 (S.D.N.Y. Sept. 20, 2019) (disclosures about breast implant products were misleadingly incomplete because they "gave investors a false impression that [the] implants were no more linked with BIA-ALCL [anaplastic large cell lymphoma] than other implants ...."

Oats Co., 129 F.3d 310, 317 (3d Cir. 1997).[5]

Defendants also told investors that the "very positive" "[c]ustomer response" to Philips' products, a large part of which comprised the Devices, contributed to significant market share gains and very strong financial performance. *See, e.g.*, ¶284. To that end, Defendants repeatedly touted the success of the Devices claiming, for example, that as of January 30, 2018, "[t]he award-winning Trilogy Ventilator as well as our compact sleep therapy system DreamStation Go ... contributed to a double-digit comparable growth in sleep and respiratory devices for the fourth quarter." ¶176. On July 20, 2020, Philips was reporting that "sales in the Connected Care business increased 14%, with double-digit growth in Sleep & Respiratory Care," "due to strong shipments of respiratory devices ... " ¶¶260-62. Defendants boasted that "[c]omparable order intake in Connected grew by 167%" in the second quarter of 2020, and that after the E30 was launched, "we immediately got orders in April, tens of thousands." ¶¶262, 267; *see similarly* ¶¶263-64, 268, 271. Similar representations touting the Devices' success due to "customer response" were made throughout the Class Period. *See, e.g.*, ¶¶275-76, 282-84.

Defendants claim that they had no duty to disclose problems with the foam (Defs' Br. at 20-22), but "[o]nce defendants cho[o]se to tout positive information to the market' about [the positive customer response to and demand of the Devices], they were 'bound to do so in a manner that wouldn't mislead investors, including disclosing adverse information that cuts against the positive information.'"). *Shenwick v. Twitter, Inc.*, 282 F. Supp. 3d 1115, 1140 (N.D. Cal. 2017)

[5] Defendants seek to evade liability for their misstatements about the E30 ventilator on the basis that the FDA authorized its sale for emergency use. (Defs' Br. at 20 n.7). But the Complaint alleges that Defendants failed to inform the FDA that the foam Philips used in the E30 ventilator was the same dangerous foam used in the other Devices, and the FDA was kept in the dark about those additional reports as well. *See*, *e.g.*, ¶¶8, 104, 107, 114. For these reasons, Defendants' argument is a red herring.

(quoting *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705–06 (9th Cir. 2016)); *see similarly City of Sterling Heights Police & Fire Ret. Sys. v. Reckitt Benckiser Grp. PLC*, 2022 WL 596679, at *19 (S.D.N.Y. Feb. 28, 2022) (market data figures accompanied by statements that the product's success has demonstrated that it is "very clearly the preferred product" on the market were actionable); *In re OSI Pharms., Inc. Sec. Litig.*, 2007 WL 9672541, at *8 (E.D.N.Y. Mar. 31, 2007) ("positive general statements" were misleading since defendants left out "adverse facts" about the drug); *Manavazian v. Atec Grp., Inc.*, 160 F. Supp. 2d 468, 481 (E.D.N.Y. 2001) (allegations "that defendants' positive characterizations of the Company's current and future business conditions were made while they were aware that an 'adverse business trend' rendered those statements misleading[,]" makes their statements false and misleading).

Defendants cite *In re Carter-Wallace Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998), for the proposition that reports of illnesses need not be disclosed because they are immaterial unless they are "statistically significant." (Defs' Br. at 21-22). But "the Supreme Court ... rejected the bright-line rule expressed in *Carter-Wallace I* by holding that the mere absence of statistically significant evidence does not demonstrate a lack of materiality." *In re Sanofi-Aventis Sec. Litig.*, 774 F.Supp.2d 549, 563 n.9 (2011), citing *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 43-44 (2011); *accord*, *In re Bayer AG Sec. Litig.*, 2004 WL 2190357, at *9 (S.D.N.Y. Sept. 30, 2004) (statistical significance is not a bright-line rule because materiality is a flexible, fact-based application); *S.E.C. v Morgan Keegan & Co.*, 678 F.3d 1233, 1249 (11th Cir. 2012) (same). Here, moreover, the problems with the Devices were identified "by [Philips'] own stud[ies] rather than [only] from events reported by third parties as in *Carter-Wallace*." *In re OSI Pharmaceuticals,*, 2007 WL 9672541, at *10. And the issues with the foam degradation were so critical, they necessitated a massive Class I product recall, resulting in Philips taking a reserve of at least 500

million euros to date.[6] About 60% of Sleep & Respiratory Care revenue derived from the sale of the recalled Devices. ¶¶17, 340. Sleep & Respiratory Care accounted for 49% of income from sales in the Connected Care segment in 2020, meaning over 8% of Company income from sales in 2020 were from sales of the at-issue devices. 2020 20-F at §6.3.2.[7]

B. Defendants Made Materially False and Misleading Statements About Regulatory Compliance and Risks

Defendants also made materially false and misleading statements about regulatory compliance and risks. Non-aspirational statements of compliance with applicable laws and regulations, like the ones Defendants made here, are actionable. *See Omnicare,* 575 U.S. at 196-97 (statements about legal compliance can be actionable); *Meyer*, 761 F.3d at 251 (defendants' "comforting [oral] statements ... about compliance measures" "could be found by a trier of fact to be ... misleading"); *see similarly Pirnik v. Fiat Chrysler Autos., N.V.*, 2016 WL 5818590, at *5 (S.D.N.Y. Oct. 5, 2016) (representation that the company was "substantially in compliance with the relevant global regulatory requirements affecting [the company's] facilities and products" was actionable); *Fed. Hous. Fin. Agency v. Nomura Holding Am., Inc.*, 104 F. Supp. 3d 441, 563 (S.D.N.Y. 2015), *aff'd sub nom*, 873 F.3d 85 (2d Cir. 2017) (representation that "[a]ll of the mortgage loans were originated ... generally in accordance with [applicable] underwriting guidelines" was actionable); *In re Bear Stearns Cos. Sec., Derivative, & ERISA Litig.*, 763 F. Supp.

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[6] Indeed, as the Second Circuit explained, a misstatement may be material as to "a particularly important segment" of a company's business, even if very small relative to the company as a whole. *Litwin v. Blackstone Grp.*, 634 F.3d 706, 720 (2d Cir. 2011).

[7] "Regardless of whether *In re Carter-Wallace* ... or its progeny imposed an affirmative disclosure obligation on [Philips] during the Class Period, the absence of an affirmative obligation does not shield [Philips] from disclosure obligations that may be imposed by other independent grounds." *Sanofi*, 774 F.Supp.2d at 563, citing *Caiola*, 295 F.3d at 331 ("The lack of an independent duty is not ... a defense to ... liability because upon choosing to speak, one must speak truthfully and accurately.").

2d 423, 459 (S.D.N.Y. 2011) (statements about regulatory compliance were actionable).

Here, Defendants represented that "Philips actively maintains Quality Systems globally that establish standards for its product design, manufacturing and distribution processes," and that "these standards are in compliance with Food and Drug Administration(FDA)/International Organization for Standardization (ISO) requirements." *See, e.g.*, ¶¶245, 293; *see also* ¶78 (representing that the E30 ventilators "compl[ied]" with "medical device quality standards"). The Complaint alleges that under multiple regulations and guidance, Philips was required to have the mechanisms in place to identify and investigate product and quality problems and take corrective actions, including making such reports to the FDA. *See, e.g.*, ¶69.

Defendants baselessly assert that the Complaint fails to particularize any facts showing why these and other similar statements were false. (Defs' Br. at 18-19). But the Complaint makes precisely such particularized allegations. It alleges that pursuant to 21 C.F.R. §820.100, Philips was required to but failed to establish and maintain proper procedures for implementing corrective and preventive actions. ¶62; *see similarly* ¶68 (citing ISO 13485:2016). For example:

- According to the FDA, CAPA INV 0988, and the related evaluations and studies, were insufficient because they failed to consider known data at that time. In Health Hazard Evaluation ER2227646 V06, Philips reported 17 complaints related to degradation of air inlet path foam. However, a search of the complaints database from 2008 to 2017 found over 175,000 total complaints with related keywords, of which 20,000 were associated with Trilogy devices. (¶102)
- A corrective action was instituted as a result of CAPA INV 0988, which required that in certain circumstances the Inlet Air Path Assembly and Removable Air Path Foam in Trilogy devices were to be replaced. This was not reported to the FDA as required under the relevant regulations. According to the FDA, Philips did not even verify whether the procedure was effective. (¶104)

See similarly ¶¶82-83, 87-88, 90-91, 94, 96-98, 103, 107-110, 113, 115-116, 120 (detailing the FDA's observations of noncompliance).

Contrary to their contention, Defendants' specific representations that Philips's Quality

Systems complied with FDA and/or ISO requirements are not mere puffery, but verifiable facts that were false and misleading when made. The cases on which Defendants rely are inapposite. Unlike here, "[t]he statements at issue in *UBS* ... were too open ended, indefinite, or subjective to be actionable under the circumstances," *In re Goldman Sachs Grp., Inc. Sec. Litig.*, 2014 WL 2815571, at *5 (S.D.N.Y. June 23, 2014), and contained qualifiers such as "aims to," "wants to," and "should." Moreover, neither in *Ong* nor in *Abbott Labs* did the plaintiffs allege specific statutes or regulations that were violated.[8] In any event, where, as here, a company states that it is in "compliance with the myriad global regulations to which it was subject," then "a reasonable investor could, and likely would, read" such statements "to mean that the company was substantially in compliance with *all* applicable regulations, including the [FD&CA] and [medical device] regulations in the United States." *Pirnik*, 2016 WL 5818590, at *5 (emphasis in original) (citing *Fed. Hous. Fin. Agency Nomura Holding Am., Inc.*, 104 F. Supp. at 563).

Relying on out-of-circuit authorities, Defendants argue incorrectly that "[o]bservations in a Form 483 do not render a defendant's statements concerning compliance misleading." Defs' Br. at 18 (citations omitted). But district courts in the Second Circuit have expressly concluded otherwise. *See*, *e.g.*, *Schaeffer v. Nabriva Therapeutics plc*, 2020 WL 7701463, at *11 (S.D.N.Y. Apr. 28, 2020) (collecting cases); *Okla. Police Pension Fund & Ret. Sys. v. Teligent, Inc.*, 2020 WL 3268531, at *14 (S.D.N.Y. June 17, 2020) (same). The Eighth Circuit, the only appellate court to have decided the issue, held that "for purposes of pleading a securities fraud claim, the

[8] Here, in contrast, the Complaint sets forth the requirements with which Philips was obligated to comply, ¶¶50–70, and further sets forth where, when, how, and why Philips failed to comply with those requirements. ¶¶80–85, 87–92, 94, 96–104, 107–10, 112–13, 115–16, 119–21, 345–79. Additionally, Defendants' statements specifically identified the FDA's Quality System Regulation by name, ¶¶70, 80, 86, 129, 153, 172, 213, 245, 293, and also identified certain ISO regulations by name and provision. ¶¶68, 80, 213, 245, 293, 390, including in its undisclosed internal testing reports. ¶¶116, 352.

issuance of a Form 483 may render a defendant's statement about its compliance with FDA regulations or cGMP false, or at least misleading ..." *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 982–83 (8th Cir. 2012). Here, moreover, the Form 483 exposed Philips' (or its subsidiaries') ***own tests and analyses***, which numerous times concluded that the foam was subject to degradation, so the findings detailed in the Form 483 report take on magnified significance.

C. Defendants' April 26, 2021, Statements About the €250 Million Reserve Were Misleading

The Complaint also alleges that Defendants' April 26, 2021 statements about the Company's initial €250 million reserve were misleading because Defendants knew or were reckless in not knowing that such a reserve "would be inadequate," ¶¶122, 296, 298, 310, in part because Defendants referenced only "the first-generation DreamStation product family," but mentioned no other product, ¶¶9–10, and thus "did not inform the market of the full extent of the issues plaguing [Philips'] devices." ¶11. As described above, from as early as 2015, Defendants had access to facts contradicting their statements.

Defendants contend that these were inactionable opinion statements. (Defs' Br. at 22–23). But in the Second Circuit, "plaintiffs can allege that a statement of opinion, without providing critical context, implied facts that can be proven false." *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 175 (2d Cir. 2020). As a threshold matter, as in *Abramson*, Defendants' statements about the initial €250 million reserve "w[ere] not framed like a statement of opinion." *Id.* at 176. Moreover, as explained above, Defendants were "reassuring [their] audience" that only the DreamStation devices were at issue when, in reality, myriad Devices were defective. *Abramson*, 965 F.3d at 176. Additionally, Van Houten emphasized that Philips was "being responsible and proactive even though the occurrence rate is very, very low." ¶307. "This context, including the specificity of the representation and the authority with which [they] w[ere] made, could lead 'a

reasonable person [to] think that a more detailed investigation lay behind the ... statement[s].'" *Abramson*, 965 F.3d at 177. Van Houten also "made his statement[s] during [Philips'] scheduled presentation" to investors, ¶¶297-300, 306-311, so that "[i]nvestors in attendance reasonably would not have interpreted [Van Houten's] statement[s] as a 'baseless, off the cuff judgment;' instead, they would have credited his statement[s] as researched and intentional, part of a well-prepared professional presentation." *Abramson*, 965 F.3d at 177.

Defendants' argument that their statements about the April 2021 reserve contained "cautionary language," (Defs' Br. at 23), does not insulate those statements from liability, as the risk of FDA noncompliance had already materialized but was not disclosed to investors. *See Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004) ("Cautionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired."). Indeed, Defendants' cautionary statements were themselves false and misleading. *See*, *e.g.*, *In re Facebook, Inc. IPO Sec. & Derivative Litig.*, 986 F. Supp. 2d 487, 516 (S.D.N.Y. 2013) ("Courts in this Circuit have held that a company's purported risk disclosures are misleading where the company warns only that a risk may impact its business when that risk has already materialized"); *accord*, *Behrendsen v. Yangtze River Port & Logistics Ltd.*, 2021 WL 2646353, at *7 (E.D.N.Y. June 28, 2021).

D. The Complaint Pleads a Strong Inference of Scienter

The key question for scienter is whether "defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation." *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000). The test is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter ...." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322-23 (2007) (emphasis in original). When considered holistically, the

Complaint's allegations plead a strong inference of scienter.[9]

1. Defendants and Other Management With Executive Responsibility Attended Meetings Where the Issues Were Discussed

Scienter is adequately pleaded. In the Second Circuit, all that is necessary to plead corporate scienter is that "the pleaded facts must create a strong inference that *someone* whose intent could be imputed to the corporation acted with the requisite scienter" or "that the statements would have been approved by corporate officials sufficiently knowledgeable about the company to know that those statements were misleading." *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008) (emphasis added); *accord*, *Loreley Fin. (Jersey) No. 3 v. Wells Fargo*, 797 F.3d 160, 177 (2d Cir. 2015).

The individual making an alleged misstatement and the one with scienter do not have to be one and the same. *See In Re JP Morgan Chase Sec. Litig.*, 363 F.Supp.2d 595, 627 (S.D.N.Y. 2005) (observing that the scienter of a vice chairman, vice president, and a managing director can be imputed to the company for its misstatements made in various public documents). "[S]cienter by management-level employees is generally sufficient to attribute scienter to corporate defendants." *In re Moody's Corp. Sec. Litig.*, 599 F. Supp. 2d 493, 515-16 (S.D.N.Y. 2009). In *Loreley Fin. (Jersey) No. 3 Ltd.*, 797 F.3d at 176-78, for example, the Second Circuit imputed to the company, for statements made by the company in offering documents, the scienter of a managing director with knowledge of the alleged undisclosed facts. Similarly, in *Richman v. Goldman Sachs Grp., Inc.*, 868 F. Supp. 2d 261, 277, 281 & n.10 (S.D.N.Y. 2012), the court imputed to the bank the scienter of its mortgage department head with respect to statements made by the bank in its Form 10-Ks and in its annual reports. Likewise, in *Pa. Pub. Sch. Emps.' Ret.*

[9] "[I]nformation from confidential witnesses [is] not needed" to plead scienter. *In re Alphabet, Inc. Sec. Litig.*, 1 F.4th 687, 707 (9th Cir. 2021).

Sys. v. Bank of Am. Corp., 874 F. Supp. 2d 341, 363 (S.D.N.Y. 2012), the court imputed the knowledge of a vice president and assistant vice president to the bank, for statements made by the bank in SEC filings, earnings press releases, a prospectus, and earnings calls.

Here, Philips acknowledged in public filings that it held regular meetings, where quality issues related to its products were discussed. ¶105. At all relevant times, Philips had a Quality & Regulatory Committee that met periodically to discuss quality and regulatory concerns related to its products. Annual Report for the year ended December 31, 2021 ("2021 20-F")[10] at 107. Significantly, Defendant Van Houten attended all the Quality & Regulatory Committee meetings held in 2018, 2019, 2020, and 2021. ¶¶105, n.2; 2021 20-F at 123. Among the topics discussed at the Quality & Regulatory Committee meetings were (i) quality and regulatory dashboards, which displayed key performance indicators for business groups and markets, measuring performance and continuous improvement to enhance quality and compliance; (ii) the status and outcome of quality investigations and related matters; (iii) complaint handling and post-market surveillance; and (iv) adherence to the Company's Quality Management Systems. Accordingly, through his personal attendance at these meetings, Van Houten was aware of the foam degradation issues that were the repeated subject of customer complaints and internal tests and analyses conducted by Philips and/or its subsidiary. Importantly, Van Houten ***admittedly learned*** that the foam in the Devices was degrading ***from post-market surveillance actions***—the very topic that was the constant subject of the Quality & Regulatory Committee meetings. ¶¶299, 306, 308, 310, 354. Post-market surveillance showed problems with the form as early as 2015, and internal tests confirmed these problems as early as 2016. *See supra* at 1-3, 5, 8; Form 483 at 3-4.

[10] On a motion to dismiss, the Court may consider "public disclosure documents required by law to be, and that have been, filed with the SEC[.] "*Bd. of Trs.* v. *Mechel*, 811 F. Supp. 2d 853, 865 (S.D.N.Y. 2011).

Moreover, and equally important, the FDA found that Philips' Sleep and Respiratory Care Business Leader ("Management With Executive Responsibility") and Head of Quality attended all the management review meetings since 2019, where the foam degradation issues were discussed. ¶374; Form 483 at 24.[11] Accordingly, "[D]efendants knew or, more importantly, should have known that they were misrepresenting material facts related to the [Devices]." *Novak*, 216 F.3d at 308.[12]

Here, the Complaint does not contain vague references to "senior leadership" of "unspecified information" that was discussed or reported, but instead singles out Defendant Van Houten and Philips' Sleep and Care Business Leader who had access to specific information in the form of reports (including market surveillance and internal reports) about the Devices, and alleges that the Individual Defendants paid close attention to the Devices and routinely commented on their features and success, demonstrating their familiarity with the products. *See supra* at 8, 10-

[11] These findings include analyses and reports prepared by Philips itself (or its subsidiary), so they are not just "observations" made by the FDA, as Defendants downplay them.

[12] Defendants' cases are inapposite. *In re Henry Schein, Inc. Sec. Litig.*, 2019 WL 8638851, at *19 (E.D.N.Y. Sept. 27, 2019) concerned vague allegations that an employee pressured manufacturers to force out lower-priced competitors at the request of senior "corporate leaders." Likewise, the allegations in *Jackson v. Halyard Health, Inc.*, 2018 WL 1621539, at *9 (S.D.N.Y. Mar. 30, 2018) contained only "vague references to 'senior leadership' and 'senior management." The plaintiff in *Plumbers' Union Local No. 12 Pension Fund v. Swiss Reinsurance Co.*, 753 F. Supp. 2d 166, 185 (S.D.N.Y. 2010) "failed to allege with particularity any contrary information that rendered the defendants' statements reckless or worse." Likewise, the plaintiffs in *In re Take-Two Interactive Sec. Litig.*, 551 F. Supp. 2d 247, 305 (S.D.N.Y. 2008) "fail[ed] to allege" that the individual whose scienter could be imputed to the company "possessed, or had access to, any specific, contemporaneous information that contradicted the company's public statements." The complaint in *In re Marsh & McLennan Cos., Inc. Sec. Litig.*, 501 F. Supp. 2d 452, 486 (S.D.N.Y. 2006) was devoid of any allegations that the individuals whose scienter could have been imputed to the company had access to reports or presentations where the issues were mentioned. Similarly, *In re Federated Dep't Stores, Inc. Sec. Litig.*, 2005 WL 696894, at *4 (S.D.N.Y. Mar. 25, 2005) involved "vague allegations of 'discussions'" and "unspecified information about Fingerhut's customer receivables, that may or may not have alerted Defendants to the problem" and failed to allege "that the internal company reports showed [problems]."

11, 17-18, 20-21 and *infra* at 23-24. Here, moreover, the Sleep and Respiratory Care Business is part of one of the three main segments of *Philips*, not of Philips Respironics (*see, e.g.*, ¶206), and the Business Leader for Sleep and Respiratory Care is an agent of *Philips* for imputation purposes.[13] At a minimum, during the relevant time, the Business Leader for Sleep and Respiratory Care held a dual role: at Philips and at Philips Respironics. Accordingly, the scienter of Defendant Van Houten and of Philips' Sleep and Respiratory Care Business Leader is imputed to Philips. *See supra* at 19-20 (discussing cases); *see also In re EZCorp., Inc. Sec. Litig.,* 181 F. Supp.3d 197 209-10 (S.D.N.Y. 2016) (scienter where witnesses explained that "management packs" containing information on lax operational practices "would definitely be shared" with leadership).

2. Other Factors Contribute to A Strong Inference of Scienter

During the Class Period, Defendants Van Houten and Bhattacharya routinely discussed the Devices, including their quality and customer reception. *See, e.g.*, 125, 172, 224, 270-71, 276, 284. These frequent discussions reflected the individual defendants' intimate knowledge about these products, further contributing to a strong inference of their scienter. *See*, *e.g.*, *In re Salix Pharm., Ltd.*, 2016 WL 1629341, at *14 (S.D.N.Y. Apr. 22, 2016) ("Defendant Derbyshire's statement concerning Salix's knowledge of precise inventory levels weigh[ted] in favor of scienter"), citing *Citiline Holdings, Inc. v. iStar Fin. Inc.*, 701 F. Supp. 2d 506, 516 (S.D.N.Y. 2010) (scienter sufficiently pleaded where defendants "told the investing public that they

[13] While not required to name the Business Leader for Sleep and Respiratory Care in the Complaint, Plaintiffs believe that, during the Class Period, the individual was John Frank. For example, zoominfo lists Frank as "Business, Sleep & Respiratory Care at Philips Group Leader" and states that "John Frank is a Business, Sleep & Respiratory Care At Philips Group Leader at Philips based in Amsterdam, North Holland." *See* *https://www.zoominfo.com/p/John-Frank/301772205* (last visited April 6, 2022). Similarly, Frank's linkedin profile distinguishes between his position at Respironics during 2004 - 2013 and his position at Philips during 2013 – December 2020. *See* https://www.linkedin.com/in/john-frank-8017404 (last visited April 6, 2022). In the event the Court deems necessary for Plaintiffs to name the Business Leader for Sleep and Respiratory Care, Plaintiffs respectfully request leave to amend the Complaint.

monitored the value of their portfolio").[14]

Defendants' high-level positions as Philips' CEO and CFO, and their access to information about the Devices, when considered with the rest of the Complaint's allegations, strengthen the inference of scienter. *See*, e.g., *Emps.' Ret. Sys.of Gov.'t of V.I. v. Blanford*, 794 F.3d 297, 306 (2d. Cir. 2015) (recklessness occurs when corporate executives "knew facts or had access to information suggesting that their public statements were not accurate"); *In re Mylan N.V. Sec. Litig.*, 2018 WL 1595985, at *12 (S.D.N.Y. Mar. 28, 2018) ("It requires no stretch of the imagination to infer that, due to their positions at the company and the importance of [the Devices] to [Philips'] operations, Defendants 'knew facts or had access to information suggesting that their public statements' about the [Devices] and the existence of adverse regulatory activity 'were not accurate.'" (*quoting Novak*, 216 F.3d 300 at 311).[15]

3. Motive Is Also Sufficiently Alleged

While allegations of motive are not required, *see Tellabs,* 551 U.S. at 325, the Complaint pleads a plausible inference that Defendants wanted to avoid or delay a recall as much as possible. For example, the Complaint alleges that the FDA investigation found that Philips Respironics (through its "Management With Executive Responsibility," which included the Business Leader of Philips' Sleep and Respiratory Care segment), failed to timely implement and take corrective

[14] *See also Institutional Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 271 (3d Cir. 2009) ("The perceived importance of margins supports an inference that [the CFO] was paying close attention to these numbers"); *S.Ferry LP v. Killinger*, 542 F.3d 776, 785-86 (9th Cir. 2008) (allegations that the individual defendants had access to relevant corporate information and admissions that defendants closely monitored information supported scienter).

[15] *See similarly In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 489 (S.D.N.Y. 2004); *Yates v. Mun. Mortg. & Equity, LLC,* 744 F.3d 874, 890 (4th Cir. 2014); *Avaya*, 564 F.3d at 270; *SEC v. Pirate Investor LLC*, 580 F.3d 233, 243 (4th Cir. 2009). Defendants also signed Sarbanex Oxley certifications that, when considered holistically, also contribute to a finding of scienter. *See*, *e.g.*, *In re Eletrobras Sec. Litig.*, 245 F.Supp.3d 450, 468-69 (S.D.N.Y. 2017).

action once it learned of the degradation issues, and failed to provide any reasonable basis for the decision not to include other Devices, which contained the same polyester polyurethane foam, in Philips' ongoing recalls. ¶¶324, 349, 373-74.

It is also plausible to infer that Defendants withheld the information to allow the Company to build up its inventory of non-defective products to avoid losing market share. Indeed, the Complaint alleges that Defendants were working on second-generation DreamStation devices that did not contain the defective foam. *See, e.g.*, ¶298. Faced with an analogous fact pattern, the First Circuit found that motive was sufficiently pleaded from allegations that led to a plausible inference that "defendants withheld [negative information about a product design] to allow the company to build up its inventory of new, non-defective products which had been made with the manufacturing change in place, in order to avoid loss of market share." *Mississippi Public Emps.' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 86-90 (1st Cir. 2008). The same plausible inference should be drawn here, and at the motion to dismiss stage any tie goes to the plaintiff. *See City of Pontiac Gen. Emps.' Ret. Sys. v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359, 372 (S.D.N.Y. 2012).

Had investors known the "full story" concerning the Devices, they would have been able to compare that information to the rosy and comforting statements Defendants made about the Devices' financial success, safety, and customer reception.[16]

E. The Claims Should Not Be Narrowed

First, Plaintiffs have standing to bring claims for all the statements alleged to be false and misleading, including those disseminated after plaintiffs purchased their shares. ¶¶4-31, 398-406. *See*, *e.g.*, *City of Sterling Heights Police and Fire Ret. Sys. v. Abbey Nat'l, PLC*, 423 F.Supp.2d

[16] As Plaintiffs have adequately pleaded a primary violation of Section 10(b), Defendants' only argument for dismissal of the secondary "control person" claims under Section 20(a) fails. *See Yannes v. SCWorx Corp.*, 2021 WL 2555437, at *8 (S.D.N.Y. June 21, 2021).

348, 359 (S.D.N.Y. 2006) ("It is proper to consider [alleged misrepresentations following plaintiff's purchase of [ADRs] where, as here, plaintiff alleges misleading pre-purchase statements and fraud on the market."). "Post-purchase statements are relevant to the course of wrongful conduct alleged by a plaintiff in a securities action and [plaintiff] has sued on behalf of the Class of persons who purchased stock during the entire Class Period." *Nicholas v. Poughkeepsie Sav. Bank/FSB*, 1990 WL 145154, at *5 (S.D.N.Y. Sept. 27, 1990); *see also In re Vivendi Universal, S.A.*, 242 F.R.D. 76, 88 (S.D.N.Y. 2007) ("it is well established that where, as here, plaintiffs allege that their losses were the result of a sustained course of conduct that propped up defendant's stock price throughout the class period, the class may be represented by an individual who purchased his shares prior to the close of the class period.") (collecting cases).[17]

Second, as the Amended Complaint makes plain, this action concerns only *Morrison*-compliant purchases.

CONCLUSION

Defendants' motion to dismiss should be denied in its entirety.[18]

Dated: April 18, 2022 Respectfully submitted,

[17] *See also Bovee v. Coopers & Lybrand*, 216 F.R.D. 596, 610 (S.D. Ohio 2003) ("when a complaint alleges an essential continuity of omissions or material misrepresentations, the claim of the class representative is considered typical for the class for the entire period from the date of the first objectionable report to the date of the full disclosure"), *quoting* Herbert & Alba Conte, 7 NEWBERG ON CLASS ACTIONS § 22.26. The only controlling authority cited by Defendants is easily distinguishable. In *Denny v. Barber*, 576 F.2d 465, 468-69 (2d Cir. 1978), the court ruled that the plaintiff was not a proper class representative because he bought stock *before any* alleged misstatements. *See Robbins v. Moore Med. Corp.*, 788 F.Supp. 179, 187 (S.D.N.Y. 1992) (distinguishing *Denny*). (Defendants' other cited case is distinguishable for the same reasons). Here, the Complaint alleges pre-November 30, 2020, misstatements and Plaintiffs bought stock *after many* of the alleged misstatements in reliance on those misstatements, through the fraud-on-the-market doctrine. Dkt. Nos. 1, 16 ¶404, 16-1.

[18] In the event the Court grants Defendants' motion to dismiss, or any part of it, Plaintiffs respectfully request leave to amend. *See Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991) ("It is the usual practice upon granting a motion to dismiss to allow leave to replead").

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